K100301

Section 5

APR 29 2010

Traditional 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 .92.

Applicant's Name and Address

Opal Orthodontics
by Ultradent Products Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
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Date Summary Prepared:	January 29, 2010

Name of the Device

Trade Name:	Opal® Bond™ Flow
Common Name:	Bracket Adhesive Resin and Tooth Conditioner
Device Classification:	II
Classification Product Code:	DYH

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate devices are: 3M Unitek's Transbond and Transbond LV (K073697) and Reliance's Flow-Tain LV (K083051).

Description of Device: Opal® Bond™ Flow is a light cure adhesive designed for bonding brackets other bondable appliances to etched enamel.

Intended Use of the Device: Opal® Bond™ Flow is a light viscosity, light cure bonding adhesive used for bonding to etched enamel and is recommended for appliances, permanent retainers, bondable bite turbos/ramps or similar applications. This product can be used for patients of all ages.

The following table shows that each of these devices are similar as test results comparing these devices show similar results. The devices are so equivalent that each of these companies follow standards that show us how to test this type of a device and in Section 18 "Performance and Bench", you will see that test results show the devices have the same technological characteristics.

Function	Opal® Bond™ Flow	Transbond LR and Supreme LV (K073697)	Reliance's Flow-Tain and Flow-Tain LV (K083051).
Shear Peel	X	X	X
Flexural Strength	X	X	X
Hardness	X	X	X
Shear Bond	X	X	X
Compressives	X	X	X
Metal Shear	X	X	X
Depth of Cure	X	X	X
Tensile Pull	X	X	X
Ambient Light	X	X	X
Sorption	X	X	X
Stain Testing	X	X	X

Similarities in the Indications for Use:

Opal® Bond™ Flow	New	Adhesive, Bracket and Tooth Conditioner	Opal® Bond™ Flow is a light viscosity, light cure bonding adhesive used for bonding to etched enamel and is recommended for appliances, permanent retainers, bondable bite turbos/ramps or similar applications.
3M Unitek's Transbond Supreme LV (K073697)	K071055	Adhesive, Bracket and Tooth Conditioner	Transbond Supreme LV Low Viscosity Light Cure Adhesive is a flowable orthodontic adhesive advantageous for indirect bonding or wherever a flowable light cure adhesive may be indicated.
Reliance's Flow-Tain LV (K083051)	K083051	Adhesive, Bracket and Tooth Conditioner	Flow Tain LV is a lower viscosity, flowable light cure orthodontic adhesive intended to be used for indirect bonding of orthodontic brackets."

Brief Description of Testing Performed

The following tests were conducted during the R & D phase on Opal® Bond MV and compared to 3M Unitek's Transbond and Transbond LV (K073697) and Reliance's Flow-Tain LV (K083051).

a. **Shear Peel** – This test shows higher adhesion onto brackets. A high number compared to our competitors is acceptable and preferred.
b. **Flexural Strength** – This test will show the strength of the bond during stress. A higher number than our competitors is good. The modulus side of this test shows the strength at which flexing the bond occurs. We prefer the product to be comparable to most of our competitors. One competitor shows a higher reading and we believe that shows brittleness in the bond.
c. **Hardness** – This test shows the hardness of the bond. We prefer to stay within our competitors range. However, one competitor shows a high reading and along with Flexural Strength, this can show brittleness.
d. **Shear Bond with bracket** – This test shows the absolute strength of the bond to the bracket. The highest value according to our competitors is acceptable.
e. **Compressives** – This test shows different forces on the resin. High numbers according to our competitors is acceptable.
f. **Metal Shear** – This test measures the strength of the product's bonding to metal. It is measured in two ways. Both numbers should be high or higher than our competitors.
g. **Depth of Cure** – This test shows how far a curing light penetrates into the cure. We want to stay at the high end of our competitors.
h. **Tensile Pull** - This test measure the force to pull a bracket off of a tooth.
i. **Ambient Light Sensitivity** – This test shows the tie that the product will cure in ambient light. It shows working time with the product and cure time of the product. We want low times in this category.
j. **Sorption** – This test shows how much water the resin absorbs. We want low readings on this test.
k. **Stain Testing** – We tested our product against our competitors to measure how much staining occurs with different fruits and spices. A score of1 was the lowest, less staining and a score of 5 was highest staining. It also shows us which products we should avoid if we don't want stained teeth!

Clinical Summary

Opal® Bond™ Flow is a resin based material that is light cured to adhere orthodontic appliances to teeth. Opal® Bond™ Flow is designed to bond the appliances effectively to enamel while allowing for easy removal at the appropriate time. The materials used in Opal® Bond™ Flow are the same as used by our predicates, 3M Unitek's Transbond and Transbond LV (K073697) and Reliance's Flow-Tain LV (K083051). These materials have been widely used by numerous manufacturer in the medical/dental industry.

In performing research for this summary, a PubMed search was conducted using the keywords "Orthodontic Bracket Bonding Materials". Twenty six articles were found, of which 7 were most relevant to Opal® Bond™ Flow and Indirect Bonding. Redundant articles and articles unrelated

to the safety and efficacy of Opal Bond MV were not included. Copies of the articles are attached to this section.

The efficacy or suitability to the intended purpose of Opal® Bond™ Flow has been demonstrated by a combination of in-house testing and side-by-side comparisons to predicate devices currently on the market. Results of our bench testing indicates that Opal® Bond™ Flow performs as well or better than the predicate devices currently on the market.

Summary
Risk/Benefit Review

Considering the safe history of our predicates, 3M Unitek's Transbond and Transbond LV (K073697) and Reliance's Flow-Tain LV (K083051). Opal®Bond™ Flow, is considered a safe medical device. Our records indicate that our predicates have been used by many dentists and large group practices in the United States and purchased by a large number of international distributors. To date, there have been no reported complaints of local or systemic adverse effects associated with the use of these products.

In conclusion, Opal® Bond™ Flow has been designed and manufactured with the intended use and claims for the product in mind. Scientific literature, etc. has been collected and evaluated to determine safety and efficacy of similar products used for the same indication. Following the clinical review as documented above, Opal Orthodontics by Ultradent Products, Inc. deems that when this device is used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of the patient and the association with its use constitutes acceptable risks when weighed against the benefits to the patient. Therefore, the product is compatible with a high level of protection of health and safety and may be released to the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
Regulatory Affairs Product Specialist
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

APR 29 2010

Re: K100301
Trade/Device Name: Opal® Bond™ Flow
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Codes: DYH
Dated: April 13, 2010
Received: April 15, 2010

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.\

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K100301

Device Name: Opal® Bond™ Flow

Indications for Use:

Opal® Bond™ Flow is a light viscosity, light cure bonding adhesive used for bonding to etched enamel and is recommended for appliances, permanent retainers, bondable bite turbos/ramps or similar applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSK

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 100301

(Posted November 13, 2003)